

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application:	10/664,489	Unit No.:	3761
Title:	Vaginal cleansing swab	Examiner:	Anderson, C. Lynne
Inventor:	Maxwell		
Filing Date:	09/17/2003	Our File No.:	01-219

Commissioner for Patents  
P.O. Box 1450  
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RESPONSE TO FINAL OFFICE ACTION

Dear Ms. Anderson:

The Applicant, by counsel, submits the following response to the Office Action from the Patent Examining Attorney dated April 6, 2006 (Office Action No. 2), regarding the application identified above ("the Application"). Please consider the following remarks supporting the granting of the patent:

I. THE EXAMINER HAS NOT SHOWN ANY SUGGESTION OR MOTIVATION TO MODIFY OR COMBINE THE REFERENCED TEACHINGS AS REQUIRED BY MPEP 2143.

Applicant urges that the references cited by the Examiner and arguments presented by the Examiner do not establish a prima facie case of obviousness under 35 U.S.C. §103(a).

The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness.... The initial evaluation of prima facie obviousness thus relieves both the examiner and applicant from evaluating evidence beyond the prior art and the evidence in the specification as filed until the art has been shown to suggest the claimed invention. (Emphasis added.) MPEP 2142.

Thus, Examiner must follow the criteria necessary to establish a prima facie case of obviousness.

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine referenced teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or

references when combined) must teach or suggest all claimed limitations. MPEP 2143.

Applicant urges that the above criteria have not been met in regard to the instant invention.

Examiner has put forward no evidence beyond conclusory statements that it would be “obvious to one of ordinary skill in the art to” modify the references. Furthermore, the ability to modify the reference does not necessarily establish a *prima facie* case of obviousness.

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680; 16 USPQ 2d 1430 (Fed. Cir. 1990); MPEP 2143.01.

The Examiner is required to provide some suggestion or motivation to combine the Fournier and Yoon references. At no time during the prosecution of this application has Examiner cited any reference which discloses the suggestion or motivation Fournier and Yoon could be combined, but has rather stated only that it “would have been obvious to one skilled in the art” without any supporting citations. Therefore, it can only be assumed that Examiner has relied on the teachings of the present application as the motivation to modify. Such use of Applicant’s own disclosure is expressly prohibited and inappropriate in a 35 U.S.C. §103 rejection. “The teaching or suggestion to make the claim combination and the reasonable expectation of success must be both found in the prior art, not in Applicant’s disclosure.” In re Vaeck, 947 F2d 488 (Fed. Cir. 1991). The prior art items themselves must suggest the desirability and thus the obviousness of making the combination without the slightest recourse to the teachings of the patent application. Without such independent suggestion, the prior art is to be considered merely to be inviting unguided and speculative experimentation, which is not the

standard with which obviousness is determined. Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d. 1200 (Fed. Cir. 1991).

The Examiner has thus used impermissible hindsight reconstruction, taking the direct teachings of the present application and filling in the gaps, which are neither evident nor even remotely suggested in the cited references. Impermissible hindsight must be avoided, and the legal conclusion of obviousness must be reached on the basis of the facts gleaned from the prior art. (See MPEP §2142).

## II. REFERENCES ARE NOT PROPERLY COMBINABLE OR MODIFIABLE IF THEIR INTENDED FUNCTION IS DESTROYED.

It is clear from the case law that if a prior art reference is cited that requires some modification in order to meet the claimed invention or requires some modification in order to be properly combined with another reference and such a modification destroys the purpose or function of the invention disclosed in the reference, one of ordinary skill in the art would not have found a reason to make the claimed modification. Thus, the CCPA and the Federal Circuit has consistently held that when a 35 U.S.C. §103 rejection is based upon a modification of a reference that destroys the intent, purpose or function of the invention disclosed in the reference, such a proposed modification is not proper and the *prima facie* case of obviousness cannot be properly made.

This issue was addressed in In re Gorden, 733 F.2d. 900, 221 USPQ 1125 (Fed. Cir. 1984), involving a blood filter assembly used during surgery and other medical procedures. The prior art at issue was a patent to French that disclosed a liquid strainer for removing dirt and water from gasoline and other light oils. In contrast to the claimed blood filter assembly, the inlet and outlet in the French device were located at the top, whereby gravity assisted in the separation of heavier oils or water. The USPTO asserted that it would have been obvious to turn the French device upside down to have the

inlet and outlet at the bottom and that no patentable distinction was created by viewing the French device from one direction and claimed assembly from the other. In rejecting the position of the USPTO, the court held:

The question is not whether a patentable distinction is created by viewing a prior art apparatus from one direction and a claimed apparatus from another, but, rather, whether it would have been obvious from a fair reading of the prior art reference as a whole to turn the prior art apparatus upside down. French teaches a liquid strainer which relies, at least in part, upon the assistance of gravity to separate undesired dirt and water from gasoline and other light oils. Therefore, it is not seen that French would have provided any motivation to one of ordinary skill in the art to employ the French apparatus in an upside down orientation. The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification.

In re Gorden, 733 F.2d at 902, 221 USPQ at 1127.

A. The intended function of the Fournier medicament and swab type applicator would be destroyed if combined with the Yoon medical device.

Examiner argues in Office Action No. 2 that it would be “obvious to one of ordinary skill in the art at the time of invention to increase the diameter of the disc-like portions of Fournier toward the tip of the swab, as taught by Yoon, to provide the swab with advantageous insertion and decreased leakage.” Applicant disagrees with this argument and further states that a review of the Fournier reference shows that if in fact this modification was made, the intended function of the Fournier medicament applicator would be destroyed.

The medicament applicator disclosed in Fournier is a multi-purpose applicator for use in the application of liquid or semi-solid compositions (see Background of Invention). The embodiment of the applicator shown in FIG. 6 of the Fournier reference shows an applicator which has a “cured polymeric foam layer 17” which ... “has been formed into outwardly extending annular ridges 24.” As

discussed in the Fournier reference, the intended purpose of the foam layer is to apply the impregnated various therapeutic compositions onto the surface area of the vaginal wall. This intended purpose of the invention is destroyed if the annular ridges of the Fournier applicator are decreased from the tip downward, as the outer surface area of the smaller impregnated foam layers would not come in contact with the vaginal wall. It is necessary for each of the ridges of the foam layers to extend outward to the same degree as the others in order to have maximum amount of foam layer with the impregnated medicine touching the surface area of the vaginal wall, so as to apply the medicine. If the annular ridges had a decreased circumference as they progressed down the applicator, it would be a waste of foam layer and medicine, as the foam layer ridges with the smaller circumference would not come into contact with the vaginal wall.

The Applicant's swab is designed to remove vaginal secretions from the vaginal cavity. While the largest disc-like portion may come into contact with the vaginal wall, the smaller disc-like portions serve to move the secretions in the vaginal cavity in a forward fashion toward the opening of the vaginal cavity.

The Yoon reference is distinct from Applicant's swab in that it is a swabbing tool which is used in endoscopic procedures. The intended function of the Yoon device shown in FIG. 18 is to prevent leakage from the surgical site into surrounding body cavities or outside the surgical site. Applicant's swab does not "prevent" leakage from the vaginal cavity but rather promotes leakage, or fluid removal, from the cavity. Unlike either of the two cited references, the Applicant's swab is intended to pull fluids out of the vaginal cavity and is used as a cleaning device, unlike Fournier and Yoon. The distinction in shape is important, as the function is entirely different.